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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/830,019	09/21/2001	Chikara Aizawa	SHIM1120	9316
28213	7590	12/29/2004	EXAMINER	
GRAY CARY WARE & FREIDENRICH LLP 4365 EXECUTIVE DRIVE SUITE 1100 SAN DIEGO, CA 92121-2133			LE, EMILY M	
			ART UNIT	PAPER NUMBER
			1648	

DATE MAILED: 12/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/830,019

Applicant(s)

AIZAWA ET AL.

Examiner

Emily Le

Art Unit

1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 09/27/04, 02/06/04, 03/05/02, 12/06/01 and 04/19/01.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-3 and 6-15 is/are pending in the application.
- 4a) Of the above claim(s) 8-12, 14 and 15 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3, 6-7, and 13 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Status of Claims***

1. Claims 1-3 and 6-15 are pending in the instant application. Claims 8-12 and 14-15 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Applicant's February 06, 2004 response. Accordingly, claims 1-3, 6-7 and 13 are currently under examination.

### ***Information Disclosure Statement***

2. The information disclosure statement filed 1/29/02 fails to comply with 37 CFR 1.98(a)(1), which requires a list of all patents, publications, or other information submitted for consideration by the Office. In the instant, a copy of the attached PTO-1449 is not found in the file. It has been placed in the application file, but the information referred to therein has not been considered.

### ***Claim Objections***

3. Claims 6 and 13 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

Claim 6 requires that the toxin be attenuated via formalin treatment. The preceding claim all ready requires that the toxin be treated via formalin treatment, i.e. claim 1 requires that a formalin group be bounded to a lysine residue.

Art Unit: 1648

4. Claim 13 requires that the toxin be attenuated by chemical treatment. The preceding claim already requires that the toxin be attenuated via chemical treatment, i.e. claim 1 requires that a formalin group be bounded to a lysine residue.

***Claim Rejections - 35 USC § 112***

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 1-3, 6-7 and 13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is unclear if claim 1 requires that the natural or attenuated toxin to have a formalin molecule bound to a lysine residue of the toxin. In the instant, the claim recites of two types of toxin, an attenuated toxin and a natural toxin. As written, it is unclear if it is the attenuated or natural toxin that must have formalin bounded to one of its lysine residue.

Should what is intended by Applicant is for the attenuated toxin to have a formalin group attached to a lysine residue that is present in amino acid sequence of the attenuated toxin, then the claim is further rendered indefinite because the claim contains limitations that are contradictory of one another. Those limitations are i) the attenuated toxin retains the lysine residue of the natural toxin; and ii) a lysine residue present in the attenuated toxin be bounded to a formalin molecule.

Additionally, should what is intended by Applicant is for the natural toxin to have a formalin toxin bounded to a lysine residue, then, the claim is indefinite because the presence of a formalin bounded to a lysine residue that is present in a natural toxin

Art Unit: 1648

would transition the natural toxin from its naturally existing form to a modified form; thereby rendering a modified toxin. A modified toxin is not the same as a natural toxin.

***Claim Rejections - 35 USC § 102***

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 1, 3, 6, 7 and 13 are rejected under 35 U.S.C. 102(b) as being anticipated by Esposito et al.

The claims are directed to an adjuvant comprising an attenuated toxin, having residual toxic activity of less than 1/2000 that of the natural toxin that correspond to the attenuated toxin. The claims require that the attenuated toxin retains serine, glutamic acid and lysine residues that are present in its corresponding natural toxin. The claims require that the attenuated toxin also further have a formalin group bounded to a lysine residue that is present in its amino acid sequence, by treating the natural toxin with formalin. The claims require that the attenuated toxin be an attenuated cholera toxin. The claims also further require that the residual toxic activity be less than 1/10000 that of the attenuated toxin's corresponding natural toxin.

Esposito et al. teaches of an adjuvant comprising an attenuated toxin, specifically, an attenuated cholera toxin. Esposito et al. obtained the attenuated cholera toxin via chemical treatment of the natural toxin with formalin.

In the instant, the adjuvant of Esposito et al. is structurally the same as the claimed invention. Additionally, the adjuvant of Esposito et al. is obtained via the same

Art Unit: 1648

attenuation technique as instantly claimed, treatment of the natural toxin that corresponds to the attenuated toxin with formalin to yield the attenuated toxin. Ergo, Esposito et al. teaches the claimed composition. Any activity that is not discussed by Esposito et al. that is appreciated elsewhere, such as a residual toxicity level of less than 1/2000 and less than 1/10000, is an inherent property of the same composition, absent evidence to the contrary.

### ***Conclusion***

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Emily Le whose telephone number is (571) 272 0903. The examiner can normally be reached on Monday - Friday, 8 am - 5:30 pm.

Art Unit: 1648

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on (571) 272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Jeffrey S. Parkin, Ph.D.  
Primary Patent Examiner  
Art Unit 1648



E. Le